

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT DAYTON**

DAYTON AREA CHAMBER OF
COMMERCE, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, *et al.*,

Defendants.

No. 3:23-cv-00156-MJN-PBS

Judge Michael J. Newman

Magistrate Judge Peter B. Silvain, Jr.

**PLAINTIFFS' RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL
AUTHORITY**

The March 1 decision of the district court in *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:23-cv-00931-CFC, 2024 WL 895036 (D. Del.), should have no effect on this Court's decision in this case. *See* Dkt. 95 (Defendants' notice of supplemental authority regarding *AstraZeneca*); Dkt. 95-1 (*AstraZeneca* slip op. ("Op.")). The *AstraZeneca* suit is very different from Plaintiffs' suit, and the *AstraZeneca* decision thus focuses on issues not presented here and, conversely, does not address many key issues that are presented here.

First, *AstraZeneca* primarily challenged CMS's guidance regarding the Inflation Reduction Act's drug price-control program. Plaintiffs here, in contrast, challenge only the constitutionality of the statute and have not brought a constitutional or statutory challenge to CMS's guidance. Most of the parties' briefing and most of the court's decision in *AstraZeneca* is therefore not relevant to this case. *See* Op. 16–34 (addressing challenges to CMS guidance).

Second, and relatedly, *AstraZeneca* did not challenge the constitutionality of the statute under the First Amendment, the Excessive Fines Clause, Congress's enumerated powers, or the Constitution's separation of powers. The *AstraZeneca* decision thus does not address any of

those claims raised by Plaintiffs here.

Third, although AstraZeneca did raise a due process challenge to the statute, there are important differences between that case and this case, as AstraZeneca did not raise—and the court did not address—key arguments that Plaintiffs have squarely presented here.

For example, while the court rejected AstraZeneca’s due process claim based on its conclusion that “participation in Medicare is not involuntary,” Op. 44, AstraZeneca did not raise, and the court did not grapple with, the arguments that Plaintiffs have presented here regarding *National Federation of Independent Business v. Sebelius (NFIB)*, 567 U.S. 519 (2012), and the unconstitutional-conditions doctrine. *NFIB* was cited only in AstraZeneca’s reply brief, and even then only one time in a single sentence at the end of that brief, and AstraZeneca did not develop any argument regarding the concept of unconstitutional conditions. *See* 1:23-cv-00931-CFC (D. Del.), Dkt. 58 (plaintiffs’ reply brief) at 50; *see generally id.* Dkt. 19 (plaintiffs’ opening brief). In contrast, Plaintiffs have argued at length that, regardless of whether Medicare in general was or is voluntary, the IRA’s price-control program is a “new program” that leaves Plaintiffs’ members “no real option.” Dkt. 64 at 21 (citing *NFIB*, 567 U.S. at 581–87); *see also id.* at 33–35; Dkt. 90 at 40–49. And Plaintiffs have relied on binding Sixth Circuit precedent applying the unconstitutional-conditions doctrine to the Due Process Clause in analogous circumstances. *See, e.g.,* Dkt. 64 at 27–28, 31–32 (citing *R.S.W.W., Inc. v. City of Keego Harbor*, 397 F.3d 427 (6th Cir. 2005)).

In addition, the *AstraZeneca* court did not address the statutory window of 11 to 23 months during which a manufacturer is legally compelled to remain in the price-control program before a withdrawal from federal healthcare programs takes effect. *See* Op. 34–44 (addressing due process claim but not mentioning this issue); Dkt. 64 at 28–30; Dkt. 90 at 49–50. The court

also did not address the fact that a manufacturer cannot withdraw a drug selected for “negotiation” from the program—on any timetable—without losing Medicare coverage for its entire corporate family’s entire portfolio of drugs. *See* Op. 34–44 (addressing due process claim but not mentioning this issue); Dkt. 64 at 15 & n.9; Dkt. 90 at 48–49. And *AstraZeneca* made no mention of *Michigan Bell Telephone Co. v. Engler*, 257 F.3d 587 (6th Cir. 2001), which is binding precedent here but not in that court.

In sum, the *AstraZeneca* decision should have no bearing on this Court’s disposition of this very different suit.

Dated: March 7, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2024, a true and correct copy of the foregoing Plaintiffs' Response to Defendants' Notice of Supplemental Authority was electronically filed with the Clerk of Court using the CM/ECF system which will send notification to all counsel of record.

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